PRODUCTORA Y COMERCIALIZADORA DE PRODUCTOS S.A. DE C.V. CALLE ZEUS No. 1105 PARQUE INDUSTRIAL KALOS DEL PONIENTE, SANTA CATARINA, N.L. C.P. 66370 Tels.: (81) 8336-9990 y 8336-0135 / Email: clientes@zumbapica.com

May 22, 2019

VIA ELECTRONIC SUBMISSION

Monet Vela
Office of Environmental Health Hazard Assessment
1001 I Street, 23rd Floor
P. O. Box 4010
Sacramento, California 95812-4010

Re: Proposed Adoption of New Chapter and Section Chapter 3: Naturally Occurring Lead in Candy Section 28500: Naturally Occurring Levels of Lead in Candy

Dear Ms. Vela:

I write on behalf of Zumbapica, a certified Mexican brand, to provide our comments on the proposed adoption of a new regulation governing naturally occurring levels of lead in candy. Zumbapica's business depends on the sale of Mexican candy that contains both chili peppers (predominantly, Guajillo peppers) and tamarind, and will therefore be directly impacted by any such regulation. Zumbapica has several concerns with respect to the proposed regulation:

1. Scientific Reliability of the Underlying Data

Based on our analysis of the supporting documentation upon which OEHHA relied (https://oehha.ca.gov/media/downloads/crnr/leadincandysupportdocument031519.pdf), it appears that most of the study focused on Anaheim-variety peppers, with a far more limited sample of Guajillo peppers included in the testing. Critically, the test results from the limited Guajillo samples – which are a dried variety and used most frequently in the manufacture of Mexican candies and snacks – differed from those from the testing of fresh Anaheim peppers. The reason is that these peppers are grown and processed differently before reaching the market. Nevertheless, the proposed regulation seems to treat them as equivalent for purposes of defining the safe harbor/threshold levels for naturally occurring lead.

PRODUCTORA Y COMERCIALIZADORA DE PRODUCTOS S.A. DE C.V. CALLE ZEUS No. 1105 PARQUE INDUSTRIAL KALOS DEL PONIENTE, SANTA CATARINA, N.L. C.P. 66370 Tels.: (81) 8336-9990 y 8336-0135 / Email: clientes@zumbapica.com

Moreover, based on the underlying data provided to the public, it appears that OEHHA is premising the regulation of a Guajillo-driven market based on its testing, more than ten years ago, of 100 peppers. The underlying data also is insufficient to identify the two brands of Guajillo peppers tested, and we therefore cannot determine whether those brands are comparable – e.g., each brand may be produced in different geographic regions with different soil conditions, one of those brands may include peppers that undergo a particular treatment before packaging or sale, etc. Simply put, a 100-pepper sample using only two brands, without more, is simply too small a sample to reach the conclusions needed to regulate, and impact the future of, a multi-million-dollar industry in California and beyond.

Based on our review of the underlying data, the proposed safe harbor/threshold level of 0.02 ppm was apparently based upon the assumption that manufacturers have the resources (whether human, financial or technical) to rehydrate the peppers, rinse the peppers in water with an unidentified mild detergent, rinse the peppers again in deionized water, and then oven-dry the peppers overnight before grinding. We can comfortably state that most, if not all, of the manufacturers in our field lack the resources to handle peppers in this manner. And even then, after following this protocol, one of the two brands tested by OEHHA saw no real change in the level of lead present: 0.05 ppm, give or take. In other words, the proposed level is unrealistic even based upon OEHHA's own tests.

Finally, while reducing the consumption of lead is critical, we were unable to identify any scientific conclusions concerning the actual health impact of 0.05 ppm versus 0.02 ppm on human health in the underlying materials – particularly when FDA-approved levels are far greater than the proposed California limit.

In sum, we believe that further and more scientifically-rigorous testing, using a much larger sample of Guajillo, and premised upon the realities facing the manufacturing industry, is needed before issuing a regulation that could seriously affect, or even compromise the viability, of the California market for these products.

PRODUCTORA Y COMERCIALIZADORA DE PRODUCTOS S.A. DE C.V. CALLE ZEUS No. 1105 PARQUE INDUSTRIAL KALOS DEL PONIENTE, SANTA CATARINA, N.L. C.P. 66370 Tels.: (81) 8336-9990 y 8336-0135 / Email: clientes@zumbapica.com

2. Technical Ability to Certify Compliance/Disincentive

As a certified producer, our company relies on testing by OEHHA-certified and OEHHA-approved laboratories in the United States. We have worked with the top laboratories in the field for almost ten years. These laboratories have represented that their limit of quantification using ICP/MS (Inductively Coupled Plasma Mass Spectrometry) is 0.05 ppm. Therefore, setting a 0.02 ppm maximum limit/safe harbor means our company, and others like it, will be unable to certify compliance because even the state-certified resources available to us cannot quantify the presence of lead below 0.05 ppm.

As a responsible market actor, Zumbapica strives to improve its processes to ensure that its products are both enjoyable and safe for consumption. But if we are unable to certify compliance based on technical limitations that prohibit us from determining whether or not a product is in compliance with a regulatory threshold of 0.02 ppm, it is simply easier for us to slap a warning on our products. This is far from our first choice. We are certain the State of California feels the same. If enacted, however, the regulation will serve as a disincentive to reduce the levels of lead and incentivize the use of warnings, instead, to ensure compliance.[1]

3. Proposition 65 Settlements/Consent Judgments

Many manufacturers, including our company, have already changed their processes and practices, and been operating in reliance on settlements with Proposition 65 relators and consent judgments vetted, approved and endorsed by the State of California. Changing the goalpost now threatens to upend these agreements and judgments, and leave us (as well as others similarly situated) in a state of legal limbo.

4. Potential Economic Impact

At this point, it is difficult to quantify the potential economic impact that reducing the safe harbor level to 0.02 ppm will have on our company or the industry. But there is little question that it will increase manufacturing costs, reduce market availability/competition, or both.

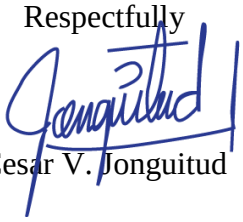
---

[1] *See* https://www.latimes.com/business/la-fi-prop65-warning-20180831-story.html (noting that 2016 Harvard and Vanderbilt Universities study found "Proposition 65 warnings […] 'are so prevalent in California that they are likely ignored by many. And consumers may mistakenly assume that items without warnings are safe even though many risky products are exempted, such as foods containing natural carcinogens.'")

PRODUCTORA Y COMERCIALIZADORA DE PRODUCTOS S.A. DE C.V. CALLE ZEUS No. 1105 PARQUE INDUSTRIAL KALOS DEL PONIENTE, SANTA CATARINA, N.L. C.P. 66370 Tels.: (81) 8336-9990 y 8336-0135 / Email: clientes@zumbapica.com

Finally, we attach a technical summary, as well as correspondence from the OEHHA-approved laboratory on which we rely for testing, noting the limitations in detection levels, for your reference. We welcome the opportunity to work with OEHHA to discuss both processes and formulations to achieve a more realistic level.

Respectfully



Cesar V. Jonguitud

PRODUCTORA Y COMERCIALIZADORA DE PRODUCTOS S.A. DE C.V. CALLE ZEUS No. 1105 PARQUE INDUSTRIAL KALOS DEL PONIENTE, SANTA CATARINA, N.L. C.P. 66370 Tels.: (81) 8336-9990 y 8336-0135 / Email: clientes@zumbapica.com

TECHNICAL SUMMARY

Dry powdered Guajillo Chili pepper

	OEHHA´s Proposed Natural Ocurring Level	FDA Requirement	*LOQ* * current USA laboratory, *by ICP/MS method***	***Average obtained Results (8 year period). USA laboratory, ICP/MS method
DRY POWDERED GUAJILLO CHILI PEPPER	0.01 ppm	0.5 ppm	0.005 ppm	0.064 ppm

Note: * *LOQ*: Limit of Quantification

**ICP /MS*: Inductively Coupled Plasma Mass Spectrometry

***Average obtained Results (8 year period): These lead content results were obtained in the period between 2011-2019 in dry powdered guajillo chili pepper, from producers with Prop. 65 Lead Control Certification Programs.

Facts:

1) Over the years, the average level of lead content obtained from different suppliers of dry powdered guajillo chili peppers is 0.064ppm, however deviations can reach even 0.1ppm in some cases. These results were gathered within a period of 8 years, considering producers with Proposition 65 Lead Control Certification Programs.
2) The Technical Support Document does not account for the differences between Sweet Green Peppers, Anaheim chili peppers, and Guajillo Chili Pepper.
3) Such peppers have physical characteristics, especially on the surface (rough and porous surfaces vs. smooth surfaces) that differ from those used by the manufacturers. These differences are related with the quality of the washing process and consequently affect lead level content. An image of the different Chili peppers is attached.

Guajillo Chili Pepper

Anaheim Chili Pepper

Sweet Green Pepper

4) In the mentioned study, fresh chili peppers were obtained from the market. A meticulous washing process was carried out with detergent, and a rinse with deionized water was given. In addition residual moisture was removed with laboratory-grade wipes. This whole process reduces the level of lead occurrence aided with the type of surface of the sample and the easiness to clean it. In a laboratory scale, the washing process differs greatly than at industrial level, were the washing process depends on continuous conveyors, sprinkled cleaning solutions and air drying.
5) Samples were dehydrated in laboratory-scale furnaces. During industrial production, dehydration is carried out by sunlight, with variations on the exposition and the environmental conditions.
6) On the study, two different methods were used to obtain the results (Multi-element *ICP/MS* and Graphite Furnace Atomic Absorption Spectroscopy *GFAAS*). Detection levels for each of the cases differ and results can show variations.

PRODUCTORA Y COMERCIALIZADORA DE PRODUCTOS S.A. DE C.V. CALLE ZEUS No. 1105 PARQUE INDUSTRIAL KALOS DEL PONIENTE, SANTA CATARINA, N.L. C.P. 66370 Tels.: (81) 8336-9990 y 8336-0135 / Email: clientes@zumbapica.com

Salt

	OEHHA´s Proposed Natural Ocurring Level	FDA Requirement	*LOQ* * current USA laboratory, *by ICP/MS method***	***Average obtained Results (3 year period). USA laboratory, ICP/MS method
SALT	0.02 ppm	2 ppm	0.05 ppm	0.054 ppm

Note: * *LOQ*: Limit of Quantification
***ICP /MS*: Inductively Coupled Plasma Mass Spectrometry
***Average obtained Results (3 year period): These lead content results were obtained in the period between 2016-2019 in salt from different suppliers.

Facts:

1) Current Limit of Quantification (LOQ) stated by the current used laboratory (Eurofins Food Integrity) is 0.05 ppm. If the natural occurring level proposed by the OEHHA is 0.02 ppm, is impossible to obtain results that complain with such level, since the specification is below the capacity of the laboratory.
2) Salt as an input sample by itself acts as an interference with the analysis method. This is the reason why laboratories do not provide detection limits below than 0.05ppm.

Sugar

	OEHHA´s Proposed Natural Ocurring Level	FDA Requirement	*LOQ* * current USA laboratory, *by ICP/MS method***	***Average obtained Results (5 year period). USA laboratory, ICP/MS method
SUGAR	0.003 ppm	N/A	0.005 ppm	0.006 ppm

Note: * *LOQ*: Limit of Quantification
***ICP /MS*: Inductively Coupled Plasma Mass Spectrometry

***Average obtained Results (5 year period): These lead content results were obtained in the period between 2014-2019 in sugar from different suppliers.

Facts:

1) Current Limit of Quantification (LOQ) stated by the current used laboratory (Eurofins Food Integrity) is 0.005 ppm. If the natural occurring level proposed by the OEHHA is 0.003 ppm, is impossible to obtain results that complain with such level, since the specification is below the capacity of the laboratory.
2) Over the years, the average level of lead content obtained from different suppliers of sugar is 0.006 ppm, however deviations can reach even 0.008 ppm in some cases.
3) On the study, results were obtained with the Graphite Furnace Atomic Absorption Spectroscopy *GFAAS* method. Commonly, the method used by laboratories is the ICP/MS method.

PRODUCTORA Y COMERCIALIZADORA DE PRODUCTOS S.A. DE C.V. CALLE ZEUS No. 1105 PARQUE INDUSTRIAL KALOS DEL PONIENTE, SANTA CATARINA, N.L. C.P. 66370 Tels.: (81) 8336-9990 y 8336-0135 / Email: clientes@zumbapica.com

Silicon dioxide

	OEHHA´s Proposed Natural Ocurring Level	FDA Requirement	*LOQ** current USA laboratory, *by ICP/MS method***	***Average obtained Results (4 year period). USA laboratory, ICP/MS method
SILICON DIOXIDE	**0.05 ppm**	**5 ppm**	**0.05 ppm**	**1.36 ppm**

Note: * *LOQ*: Limit of Quantification
**ICP /MS*: Inductively Coupled Plasma Mass Spectrometry
***Average obtained Results (4 year period): These lead content results were obtained in the period between 2015-2019 in silicon dioxide samples.

Facts:

1) Average obtained results show that within 4 years of samples analyzing, levels below FDA requirements are reached (1.36ppm). OEHHA´s proposal differs greatly from FDA requirements, such decrease would make it impossible to obtain materials that comply with the regulation.

Titanium dioxide

	OEHHA´s Proposed Natural Ocurring Level	FDA Requirement	*LOQ** current USA laboratory, *by ICP/MS method***	***Average obtained Results (4 year period). USA laboratory, ICP/MS method
TITANIUM DIOXIDE	**2.5 ppm**	**10 ppm**	**0.005 ppm**	**3.94 ppm**

Note: * *LOQ*: Limit of Quantification
**ICP /MS*: Inductively Coupled Plasma Mass Spectrometry
***Average obtained Results (4 year period): These lead content results were obtained in the period between 2015-2019 in titanium dioxide samples.

Facts

1) Average obtained results show that within 4 years of samples analyzing, levels below FDA requirements are reached (3.94 ppm). OEHHA´s proposal differs greatly from FDA requirements, such decrease would make it impossible to obtain materials that comply with the regulation.

PRODUCTORA Y COMERCIALIZADORA DE PRODUCTOS S.A. DE C.V. CALLE ZEUS No. 1105 PARQUE INDUSTRIAL KALOS DEL PONIENTE, SANTA CATARINA, N.L. C.P. 66370 Tels.: (81) 8336-9990 y 8336-0135 / Email: clientes@zumbapica.com

EXHIBIT A

De: JenniferBraucht@eurofinsUS.com <JenniferBraucht@eurofinsUS.com>
Enviado el: martes, 11 de septiembre de 2018 06:25 p. m.
Para: Laura Treto <desarrollo@zumbapica.com>
Asunto: RE: Lead information [Case: 00147857]

Hello Laura,

Please see below for expected or attainable general LOQs for each matrix. LOQs may be elevated slightly due to performance of internal standards or digestion based on specific material blends.

We do not provide a method LOD, however our Low Lead standard is 0.0250 ng/ml.

LOQs are based on the low standard, sample weights for digestion, final volume of 50 mL and dilutions prior to analyses.

INSUMOS	The Method Detection Limit	Limit of Quantification (LOQ)	UNIDAD DE MEDIDA
CHILLI POWDER		0.005	Mg/Kg y/o ppm
SALT		0.050	Mg/Kg y/o ppm
SUGAR		0.005	Mg/Kg y/o ppm
WATER		0.001-0.005 (depends on dissolved solids	Mg/Kg y/o ppm
SILICON DIOXIDE		0.050	Mg/Kg y/o ppm
TEJOCOTE PULP		0.005	Mg/Kg y/o ppm
PRODUCT FAMILIES:	The Minimum Detection Limit	Limit of Quantification (LOQ)	Mg/Kg y/o ppm
SPICY CANDY POWDER		0.005	Mg/Kg y/o ppm
FRUIT BASE CONFITED CANDY WITH CHILI		0.005	Mg/Kg y/o ppm
CANDY PASTE WITH CHILI		0.005	Mg/Kg y/o ppm
FRUIT BASE CANDY PASTE WITH CHILI		0.005	Mg/Kg y/o ppm
SEASONING		0.050	Mg/Kg y/o ppm
CONFITED GUMMIES WITH CHILI		0.005	Mg/Kg y/o ppm
FRUIT BASE PULP WITH CHILI		0.005	Mg/Kg y/o ppm
CONTACT MATERIAL:	The Minimum Detection Limit	Limit of Quantification (LOQ)	Mg/Kg y/o ppm
BIORENTED POLYPROPYLENE/BIORENTED POLYPROPYLENE (BOPP/BOPP)		0.025	Mg/Kg y/o ppm
BIORENTED POLYPROPYLENE/POLYETHYLENE (BOPP/PE)		0.025	Mg/Kg y/o ppm
BIORENTED POLYPROPYLENE FRONT PRINT		0.025	Mg/Kg y/o ppm
BIORENTED POLYPROPYLENE WITHOUT PRINT		0.025	Mg/Kg y/o ppm
POLYESTER / POLYETHYLENE (PET /PE)		0.025	Mg/Kg y/o ppm
POLYPROPYLENE		0.025	Mg/Kg y/o ppm
POLYSTYRENE		0.025	Mg/Kg y/o ppm
POLYESTER		0.025	Mg/Kg y/o ppm
HIGH DENSITY POLYETHYLENE		0.025	Mg/Kg y/o ppm

Please let me know if you need further information.

Kind regards,

Jennifer Braucht
Client Service Associate
Eurofins Food Integrity & Innovation

E: JenniferBraucht@EurofinsUS.com
P: 608-210-5529
3301 Kinsman Blvd, Madison, WI 53704

eurofins